

**REMARKS**

Claims 1-4, 6, 8-9, 11-15, and 22 are pending in the instant application. Claims 1, 11, 12, and 15 have been amended. Support for the amendments may be found in paragraph [0067]. Claim 7 has been cancelled without prejudice or acquiescence.

The following issues are outstanding in the instant application:

- Claims 1-4, 6-9, 11-15, and 17-22 have been rejected under 35 U.S.C. 103(a) as allegedly being obvious over U.S. Patent No. 4,851,221 (Pak *et al.*) in view of Mitchell, W.D. *et al.* "The Effect of Oral Calcium on Cholesterol Metabolism," Journal of Atherosclerosis Research, Vol. 8, pp. 913 – 922, 1968 (Mitchell *et al.*) or "Calcium and Serum Cholesterol" Nutrition Review Vol. 25, No. 10, pp. 298 – 300, 1967. (Nutrition Review).

**35 U.S.C. § 103 issues**

The Examiner has rejected claims 1-4, 6, 8-9, 11-15, and 22 under 35 U.S.C. § 103 as allegedly obvious over Pak *et al* in view of Mitchell *et al.*, or Nutrition Review. Applicant respectfully traverses.

**I. The references do not teach all the limitations of the claimed invention**

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).. Pak *et al*, Mitchell *et al.*, or Nutrition Review do not teach administering a pharmaceutical composition, and measuring the high-density lipoprotein level in said woman, or measuring the ratio of high-density lipoprotein to low-density lipoprotein in said woman, whereby treatment is continued for at least about 2 months if the high-density lipoprotein level in said woman, or the ratio of high-density lipoprotein to low-density lipoprotein is increased.

As all the limitations of the claimed invention are not taught by the cited references, the obviousness rejection should be withdrawn.

**II. The references teach away from the claimed invention**

As the Examiner is no doubt aware, it is inappropriate to combine references where the references teach away from the invention. A "reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

See the Nutrition Review reference cited by the Examiner. "There is no evidence that this effect is maintained for longer than three or four weeks, and there seems to be no justification for using oral calcium as a means of reducing serum cholesterol levels."

(Abstract) This reference clearly teaches away from administration of oral calcium for longer than three or four weeks.

See also the Mitchell *et al.* reference "The serum cholesterol and triglyceride levels showed little change from the basal levels during the calcium supplementation period." (Abstract). Mitchell *et al.* also clearly indicates a viewpoint of one with skill in the art that calcium supplementation has no effect on serum cholesterol, thus teaching away from the instant claims.

As the combination of Pak *et al* and Mitchell *et al.*, or Nutrition Review is inappropriate because the references teach away from the claimed invention, the obviousness rejection should be withdrawn.

### **III. The references indicate clear skepticism, and are thus evidence of nonobviousness of the claimed invention**

Furthermore, skepticism in the art is relevant and persuasive evidence of nonobviousness. See *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881, 45 USPQ2d 1977, 1981 (Fed. Cir. 1998). Both references cited by the Examiner as combineable with Pak *et al.* show clear skepticism of the merits of the invention. Thus, not only are the references inappropriate for combination with Pak, but the references in and of themselves provide evidence of nonobviousness. In particular, the Nutrition Review reference goes so far as to say there is "no justification for using oral calcium as a means of reducing serum cholesterol levels."

Faced with such clear evidence of skepticism by the cited references of the merits of the instant claims, the obviousness rejection should be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Please charge our Deposit Account, No. 06-2375, in the amount of \$450.00 to cover the fee for a two-month extension of time. Applicant believes no additional fee is due with this response. However, if a fee is due, please charge any additional fees to our Deposit Account No. 06-2375, under Order No. HO-P02194US0 from which the undersigned is authorized to draw.

Dated: February 22, 2005

Respectfully submitted,

By   
Jila Bakker, Registered Patent Agent  
Registration No.: 53,962  
FULBRIGHT & JAWORSKI L.L.P.  
1301 McKinney, Suite 5100  
Houston, Texas 77010-3095  
(713) 651-5151  
(713) 651-5246 (Fax)  
Attorneys for Applicant